Centers for Medicare & Medicaid Services) billing code based on a medical examination of a patient, including:

electronic means for automatically determining intermediate and final codes based upon information in addition to those codes that is sufficiently detailed to support HCFA billing requirements.

92. The apparatus of Claim 91, including means for manually overriding the calculated HCFA billing code.

93. The apparatus of Claim 91, in which said electronic means also solicits from a user data usable for purposes other than HCFA billing code calculations.

Remarks

Preliminarily, because some of the remarks herein relate to the United States Health Care Financing Administration (or HCFA), Applicant notes for the record that HCFA is now called "Centers for Medicare & Medicaid Services" (see, for example, the website www.hcfa.gov). Accordingly, the discussion herein regarding HCFA is intended to include as well "Centers for Medicare & Medicaid Services."

Applicant thanks the Examiner for agreeing that additional claims should be considered beyond those posed in the Examiner's restriction requirement. For the record in that regard, it appears that there is a typographical error in the Office Action at page 2, in the second l. of paragraph 2. The number "76" at the beginning of that l. apparently should be "77" to conform to the previous filing by Applicant and to be consistent with the remainder of the Examiner's Office Action. As a further related point

of clarification for the record, the second paragraph of detail section 2 of the Office Action appears to use the "old" claim numbering (without the numbering "bump up" of 9), so that the "additional" claims being considered (under the "bumped up" numbering scheme) are actually Claims 77-82, 84, 85, 88, and 89. These are in "addition" to Claims 49-73 (again, using the "bumped up" numbering scheme).

Accordingly, Applicant is proceeding on the assumption that Claim 76 was not considered by the Examiner in the most recent Office Action, as being subject to the Examiner's restriction. If the Examiner intended otherwise, Applicant would respectfully request an opportunity to respond as to Claim 76 as part of a further non-final Office Action.

Alternatively, if the Examiner considered Claim 76 in the Office Action, Applicant could not locate any detailed rejection of that Claim 76. Accordingly, under that alternative approach, Claim 69 appears to in fact be allowable. Applicant respectfully requests clarification in that regard (to the extent that the Examiner continues or interposes any new rejections in this application), and submits that (depending on the Examiner's position) Applicant may need to be afforded the opportunity to review any such rejection as part of a further non-final Office Action, and to respond to that rejection in due course.

Also in that second paragraph of detail section 2 of the Office Action, Applicant assumes that the Examiner intended to use "Group IV" throughout the paragraph instead of the two references to "Group II" (Group (II would have refers to Claim 74 under the "bumped up" numbering scheme). Applicant has proceeded herein

on that assumption. If the Examiner believes otherwise, Applicant respectfully submits that Applicant should be afforded the opportunity to review any such different position as part of a further non-final Office Action from the Examiner, and to respond to that different position in due course.

In addition, Applicant did not find in the Office Action any details regarding the rejection (indicated on the Office Action Summary page) of Claim 69. Accordingly, Applicant respectfully submits that it cannot proceed herein except on the assumption that Claim 69 is in fact allowable. If the Examiner believes otherwise, Applicant respectfully submits that Applicant should be afforded the opportunity to review any such rejection as part of a further non-final Office Action, and to respond to that rejection in due course.

Applicant was also somewhat unclear as to the status of Claim 55, which is indicated on the Summary sheet and in the third paragraph of detailed section 8 as being rejected, but is not included in the list of rejected claims in the first paragraph of detailed section 8. In an excess of caution, Applicant proceeds below based on the detailed rejection in the third paragraph of detailed section 8, and assumes that the Examiner intended the rejection to be an assertion of obviousness (Dorne in view of Kraftson). If the Examiner intended otherwise, Applicant again respectfully submits that Applicant should be afforded the opportunity to review any such rejection as part of a further non-final Office Action, and to respond to that rejection in due course.

Also, in the first two paragraphs of section 6 of the detailed Office Action, the Examiner articulates rejections of Claim 87, even though the Summary page and the

detail section 2 both indicate that Claim 87 has been restricted and is not being considered. In order to preserve his rights as to Claim 87, Applicant presents remarks regarding same hereinbelow.

Additionally, it appears that there is a typographical error in the paragraph before detailed section 6. In rejecting Claim 54, the Office Action refers to Claim 42, a claim which is no longer pending. Applicant respectfully requests clarification in that regard, and notes that there is no other basis in the Office Action for rejection of pending Claim 54. Among other things, the rejection's reference to "claim 42" could be intended to be: (a) "claim 52" (with a typographical error resulting in the "4" instead of the hypothetically intended "5"); (b) "claim 51" (based on the "bump up" of 9 that would make "42" increase by 9 to "51"); or (c) something else entirely. Accordingly, Applicant again respectfully submits that, if the Examiner intended some other claim to be listed in the rejection (besides "claim 42"), and if the Examiner continues or posits new rejections of the application, Applicant should be afforded the opportunity to review any such rejection of Claim 54 as part of a further non-final Office Action, and to respond to that rejection in due course.

Turning now to the actual rejections, Applicant preliminarily notes that the Examiner's rejections are based on three patents (Dorne, Kraftson, and Letzt) alone and/or in various combinations. More specifically, the Examiner has rejected:

(1) Claims 49, 54, and 88 under 35 U.S.C. §102(b) as being anticipated over Dorne (U.S. Pat. No. 5,325,293). As indicated above, Applicant respectfully submits that he should not be forced to "guess"

the intended basis of the rejection as to Claim 54 (in view of the Office Action's indication that the rejection is based on a non-pending claim 42), and therefore has not responded to that rejection herein.

(2) Claims 57-62, 64-68, 70-73, 79, and 87 under 35 U.S.C. §102(e) as being anticipated by Kraftson et al. (U.S. Pat. No. 6,151,581);

(3) Claims 50-53, 56, 63, 77-78, 80, and 89 under 35 U.S.C. §103(a) as obvious over Dorne in view of Kraftson et al. (as indicated above, it also appears that the Examiner intended this rejection to cover Claim 55 as well);

(4) Claim 71 under 35 U.S.C. §103(a) as obvious over Kraftson et al. in view of Letzt et al. Applicant presumes that the Office Action contains a typographical error at this location (Section 9 of the Office Action) and that instead the Examiner intended this rejection to be directed to Claim 70. Among other things, Letzt does not have anything to do with the HCFA limitation in Claim 71 (as noted elsewhere herein), and the only pending claim that includes "fifty percent" (mentioned in the third line of the second paragraph of section 9 of the Office Action) is Claim 70. In any case, as explained elsewhere, Letzt is certainly inapposite to Applicant's HCFA limitations and does not teach the use of a timer in connection therewith (and certainly does not teach to compare and calculate

regarding any percentage of time spent on one activity as part of an entire session) Letzt instead focuses on a system that (by way of example) alerts patients to take their medications at certain times (see, e.g., the first two sentences of Letzt's Abstract); and

(5) Claims 81, 82, 84, and 85 under 35 U.S.C. §103(a) as obvious over Dorne in view of Letzt et al.

Some of Applicant's specific responses regarding the apparent shortcomings of those specific rejections are detailed below. For the sake of economy and clarity, however, Applicant has focused herein on the allowability of the pending independent claims. Once that has been established, all claims depending from those allowable claims will themselves be allowable.

With the qualifications set forth above (such as certain claims apparently already being allowable), and as the claims are amended herein, Applicant respectfully traverses the Examiner's rejections, as more fully explained herein.

Among other things, and as more fully explained below, none of the references, alone or in any permissible combination, disclose or make obvious Applicant's claimed combination of elements including:

"electronic means to repeatedly prompt for information and record that information, said prompts being usable in real-time by a physician/user interacting with a patient to help guide the physician/user during said interaction with the patient and to remind the physician/user regarding specific points of inquiry that may be relevant to further

examination of that patient, said prompts soliciting underlying information usable for calculating a description of the medical services being provided rather than said prompts soliciting the physician/user for the medical service—code itself, said underlying information being necessary for determining and/or supporting the medical services code for purposes of the physician/user's eventual billing for the services" (see, for example, Claim 49 as amended).

The same is true of Applicant's claims such as Claim 58. Specifically, none of the references, alone or in any permissible combination, disclose or make obvious Applicant's claimed combination of elements including:

> electronic means for recording information during the medical examination, said information including at least sufficient details to support billing requirements imposed by HCFA instead of just a conclusory description of the medical services;
>
> electronic means for automatically determining, based upon said details, intermediate HCFA code values for sub-parts of the examination; and
>
> electronic means for automatically determining, based upon said details, an appropriate final HCFA billing code from the intermediate HCFA code values.

Among other things, HCFA billing requirements are not satisfied by Dorne's "raw codes" or the conclusory description of the medical services that those raw codes represent. Indeed, a physician might be committing Medicare fraud were he to only include Dorne's raw codes within his record-keeping, since Dorne teaches delineation of the procedure codes in the examination record but does teach the provision of detailed documentation regarding what the physician had done during each portion of the procedure. HCFA rules clearly indicate that the raw, intermediate and final codes are not sufficient to justify a particular submitted bill. Rather, HCFA rules make it necessary to document the details of what was performed to accomplish each procedure reflected in a procedure code in the bill. In contrast, Applicant's invention prompts for the underlying and/or further HCFA-required details that Dorne's system does not accommodate.

To meet HCFA requirements in that regard, the "Dorne" physician instead would apparently have to maintain his or her physician's notes or similar information in some location and/or form separately from Dorne's system. Had Dorne appreciated Applicant's invention in that regard (or even appreciated the need for a solution such as Applicant's), the Dorne patent somewhere would have described, among other things, his system as including a list of detailed suggested questions for the radiologist to ask the patient, and a list of detailed suggested points for examination by the radiologist (e.g., look in the ears, listen to the heart, etc.), as well as the ability for the radiologist to record in detail virtually every medical action performed as part of the radiological procedure. Dorne then would have taught using that detailed recorded information (rather than the

conclusory "raw" code itself) to calculate the E&M or other code based on that detailed information. Dorne did not do, or suggest, or apparently even appreciate the need for or benefit of, any of those things. In contrast, Applicant's invention does.

Perhaps as importantly regarding the Examiner's rejections based on the Kraftson and Letzt references, Applicant respectfully submits that neither Kraftson and Letzt includes any mention of: (1) the Health Care Financing Administration (now called Centers for Medicare & Medicaid Services, as noted above); (2) HCFA; or (3) government billing codes/programs. Accordingly, Applicant respectfully submits that those references have little, if any, relevance to the patentability of Applicant's claimed invention as it relates to HCFA, especially as Applicant's claims are amended herein.

Among other things, the complexity of those HCFA codes, the central nature of their function within the present medical services industry, and other factors are not within any aspect of the disclosures of Kraftson and Letzt. Instead, Kraftson is focuses on "patient clinical information and patient satisfaction information received from a group of physician practices to provide practice performance information" (col. 2, l. 52-56). By way of example, Kraftson teaches surveying patients regarding, among other things, the patient's opinion (on a scale of 1-5) of the "Availability of convenient parking/public transportation" (col. 6, l. 62-67). As indicated above, Letzt is similarly inapposite to Applicant's invention, focusing on a system that (by way of example) alerts patients to take their medications at certain times (see, e.g., the first two sentences of Letzt's Abstract).

Again, nothing in Dorne, Letzt, or Kraftson, or any prior art of which Applicant is aware, alone or in any permissible combination thereof, discloses or makes obvious Applicant's pending claims.

Dorne is directed to a system that allows a "user" (someone other than a "busy physician", such as a staff person) to correlate CPT codes with medical procedures performed during a patient examination (see, e.g., Dorne, col. 3, l. 4-15). For example, the "user enters PLANNED examinations on or before the date of the examination, which [entry of information] can commonly be done by clerical personnel based on information received from the initial appointment conversation or from an X-ray requisition" (col. 8, l. 25-30). Similarly, Dorne teaches that the "user typically recalls the examination record after the radiologist has performed the examination, and modifies the data, if necessary, to reflect what procedures the radiologist actually performed." Dorne, col. 8, l. 49 et seq.

Throughout Dorne, the focus is on a non-doctor entering the information (or a doctor doing it at some time other than during the actual examination of the patient). Specific examples of Dorne's focus in this regard include the user selecting the desired examination record and then entering "the procedures that where [sic – should be were] involved during the patient examination." Col. 11, l. 31-33. Clearly, Dorne's teachings were focused on computer hardware and software being used at times other than during the examination (such as after the examination) to calculate various codes.

Perhaps the best example of this limitation in Dorne is Dorne's own emphasis on its REVIEW function:

performed (for instance, at least at the time of the procedure, the radiologist presumably knows that angioplasty has been performed on three lesions stemming from the renal artery). Dorne's assumption (that the "user" accurately and completely receives information from the radiologist) itself may not be accurate (or at least not very common) in the real world of doctors and their staff providing medical services to patients. At the very least, Dorne's approach in that regard continues to include substantial opportunity for inaccurate or incomplete communication between the doctor and his staff/assistant/user. By way of example, if the doctor remembers the procedure accurately and correctly at the time of reporting same to the "user", the doctor's communication of that information to the user might be inaccurate, incomplete, or even indecipherable (in view of the stereotypical bad handwriting and/or mumbled recorded dictation by doctors).

Second, even if that information is correctly and completely communicated by the doctor to the doctor's "user", Dorne's process differs from at least many of Applicant's claimed embodiments, in that Dorne uses that relatively conclusory "medical procedure" (Dorne's "raw data") to look up the CPT codes that correspond to what the doctor/radiologist has done. Thus, in Dorne, there is a direct correspondence between what the radiologist's assistant selects and what appears in the final code. Again, Dorne presumes that the doctor is able to identify (completely and accurately) the proper "medical procedure".

Applicant's invention provides advances on both these issues. Among other things, the relevant information can be entered and recorded by the doctor/user

during the patient interview/treatment itself (in real-time), eliminating or greatly reducing the risk of miscommunication or inadvertent omissions that are present in Dorne's approach. Moreover, Applicant's prompts solicit information that is "independent of the description of the medical services". Accordingly, Applicant's invention permits the user/doctor to proceed through the interview/data acquisition/input process) without knowing the particular "medical procedure" terminology that eventually might be assigned (for billing purposes) to the particular services being provided. The prompts even remind the user/physician regarding possible additional areas or more detailed levels of inquiry, providing the opportunity to improve the quality of the medical services delivered.

As mentioned above, Applicant will not here attempt to comprehensively list Applicant's reservations regarding the Examiner's asserted rejections of Applicant's dependent claims. At least one, however, is sufficiently short and simple to merit mention.

The Examiner has relied upon Letzt in rejecting various claims regarding the "timer" functionality of Applicant's invention (see, e.g., the Examiner's apparent rejection of Claim 70 regarding "a timer for tracking total time and patient counseling time during said patient encounter"). Letzt does not provide a sufficient basis for the rejection. Among other things, Letzt does not teach either tracking total time or patient counseling time. Instead, Letzt teaches using a "timer" as an alarm clock to remind a patient to take some action (for example, Letzt uses a timer to control the playing of voice recordings). This simply does not teach or make obvious Applicant's claimed "timer"

functionality, especially in the context of using same to calculate billing codes based on those tracked times.

In view of the extensive analyses of the prior art and its lack of apposite teachings supporting the Examiner's anticipation and obviousness rejections, and in view of the amendments set forth above, it is thought that the application is now in condition for allowance, notice whereof is respectfully requested of the Examiner.

Respectfully submitted,

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the Claims:

Please amend the Claims as follows:

49. (Amended) Apparatus for gathering medical information regarding a patient and generating a billing code related to that information, including:

electronic means to repeatedly prompt for various information and record that information, said prompts being usable in real-time by a physician/user interacting with a patient to help guide the physician/user during said interaction with the patient and to remind the physician/user regarding specific points of inquiry that may be relevant to further examination of that patient, said prompts soliciting underlying information regarding the details of the medical service being provided, said underlying information being usable for calculating a medical service code based upon said underlying information rather than said prompts soliciting the physician/user for the medical service code itself, said underlying information being necessary for determining and/or supporting the medical services code for purposes of the physician/user's eventual billing for the services;

processing means for calculating intermediate values based on said recorded information;

processing means for using said intermediate values to generate said billing code.

51. (Amended) A method for gathering a patient's data and using that data in ~~subsequently~~ generating a billing code, including:

providing an electronic computer to prompt an information gatherer to gather information that at least includes information~~is potentially~~ relevant to calculating the billing code, said computer prompts being usable in real-time by the information gatherer interacting with a patient to help guide the information gatherer during said interaction with the patient and to remind the information gatherer regarding specific points of inquiry that may be relevant to further examination of that patient, said prompts soliciting underlying information usable for calculating a description of the medical services being provided rather than said prompts soliciting the information gatherer for the description of the medical services itself, said underlying information being independent of the description of the medical services for purposes of the eventual billing for the services;

obtaining and recording that information;

repeating said prompting, obtaining, and recording steps; and

electronically calculating a desired billing code from said gathered data.

55. (Amended) A method of calculating a medical billing code that complies with the requirements of the United States Health Care Financing Administration, including:

providing an electronic computer or scannable form;

prompting the information gatherer via said electronic computer or said scannable form to gather information that ~~is potentially~~at least includes information relevant to calculating the billing code, said computer prompts being usable in real-time by the information gatherer interacting with a patient to help guide the information

gatherer during said interaction with the patient and to remind the information gatherer regarding specific points of inquiry that may be relevant to further examination of that patient, said prompts soliciting underlying information usable for calculating a description of the medical services being provided rather than said prompts soliciting the information gatherer for the description itself of the medical services, said underlying information being independent of the description of the medical services for purposes of the eventual billing for the services;

obtaining and recording that information into said electronic computer or said scannable form;

repeating said prompting, obtaining, and recording steps; and

electronically calculating a desired billing code from said gathered data.

57. (Amended) An integrated electronic system for conducting a medical interview of a patient and contemporaneously calculating an appropriate government billing code based on that interview, including:

electronic means for prompting an interviewer to make a series of inquiries, said means optionally using at least some of the preceding responses in calculating further prompting for inquiries to make of the patient, said means being usable in real-time by the interviewer interacting with a patient to help guide the interviewer during said interaction with the patient and to remind the interviewer regarding specific points of inquiry that may be relevant to further examination of that patient, said prompts soliciting underlying information usable for calculating a description of the medical services being provided rather than said prompts soliciting the

interviewer for the description of the medical services itself, said underlying information including information independent of the description of the medical services for purposes of the eventual billing for the services;

electronic means for recording the patient's response or other information regarding the prompted inquiry; and

electronic means for calculating the government billing code based on information recorded from the medical interview.

58. (Amended) Apparatus for electronically calculating an appropriate United States Health Care Financing Administration (HCFA) billing code based on a medical examination of a patient, including:

electronic means for recording information during the medical examination, said information including at least sufficient details to support billing requirements imposed by HCFA instead of just a conclusory description of the medical services;

electronic means for automatically determining, based upon said details, ~~recording~~ intermediate HCFA code values for sub-parts of the examination; and

electronic means for automatically determining, based upon said details, ~~calculating~~ an appropriate final HCFA billing code from the ~~recorded~~ intermediate HCFA code values.

59. (Amended) Electronic apparatus for use in connection with an encounter between a medical practitioner and a patient, comprising:

electronic means for prompting the medical practitioner regarding data to be obtained from the patient regarding patient care and corresponding HCFA billing codes, said data including at least sufficient details to support billing requirements imposed by HCFA instead of just a conclusory description of the medical services;

means for storing said data from the patient;

a menu section comprising at least one of history, physical examination, and medical decision making questions, said menu section related to said means for prompting the medical practitioner;

payer mandated requirement codes;

scores based in part on results from responses to said menu section;

algorithm for linking and processing said requirement codes with said scores; and

resultant code based in part on said linked and processed requirement codes and scores.

68. (Amended) Apparatus for compiling medical data and generating claims consistent with payer mandates, comprising:

electronic means for displaying topics of inquiry for use with a patient during a patient encounter, said topics of inquiry including at least sufficient details to support billing requirements imposed by said payer mandates instead of just a conclusory description of the medical services;

data forms for collecting and storing data from said patient encounter, said data comprising patient responses and user generated text information based in part on said patient encounter;

codes representative of at least one of billing, procedure, and documentation requirements;

algorithm for linking, comparing, and computing said collected data with said requirement codes; and

resultant code based in part on said linked, compared, and computed data.

The following Claims have been added:

91. Apparatus for electronically calculating an appropriate United States Health Care Financing Administration (HCFA; now called Centers for Medicare & Medicaid Services) billing code based on a medical examination of a patient, including:

electronic means for automatically determining intermediate and final codes based upon information in addition to those codes that is sufficiently detailed to support HCFA billing requirements.

92. The apparatus of Claim 91, including means for manually overriding the calculated HCFA billing code.

93. The apparatus of Claim 91, in which said electronic means also solicits from a user data usable for purposes other than HCFA billing code calculations.